DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

91225d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-55

April 30, 2001

Louis Larson Jr., President
Larson's Dairy, Inc.
400 NW 5th St.
Okeechobee, FL 34972

Dear Mr. Larson:

An investigation of your dairy farm #5 at the above address conducted by our investigator Courtney Hunt on March 27 and 28, 2001, confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about February 12, 2001 you sold a dairy calf, identified by back tag number 1214 and USDA sample number 281022 for slaughter as human food by [redacted] USDA analysis of tissue samples collected from that animal identified the presence of Neomycin in the kidney of the animal at a level of 153.12 ppm. A tolerance of 7.2 ppm has been established for residues of Neomycin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are inadequate to ensure that medicated animals bearing potentially harmful drug residues are prevented from entering the food supply. Specifically, you fail to keep medication records which document the administration of medicated milk and adherence to the proper withdrawal time to permit depletion of potentially hazardous residues from the edible tissues. Food from animals held under these conditions is adulterated.

You are adulterating the drugs BIOSOL (Neomycin Sulfate) and Aureomycin (Chlortetracycline) that your firm uses on dairy calves within the meaning of Section 501(a)(5) when you fail to use the drugs in conformance with their approved labeling. Your use of these drugs without following the labeled withdrawal period causes the drugs to be unsafe to use.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations and prevent the recurrence of similar violations. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District